K011369

MAY 2 9 2001

510(k) Summary

Special 510(k) summary of safety and effectiveness

Company information
Safety Syringes, Inc.
1925 Palomar Oaks Way, Suite 204
Carlsbad, CA 92008 USA

Device Identification
Trade Name – UltraSafe Passive™, X-Series, Needle Guard – Models X50, X100, X100L, X150, X225, X300, X500
Classification Name – Syringe, Piston (accessory)
Classification – Class II
Product Code – 80 FMF

Predicate Device
The UltraSafe® Injection System Needle Guard – Models B50, B100, B100L, B150, B225, and B300

Device Description
The UltraSafe Passive™, X-Series, Needle Guard is an accessory for ISO Standard pre-filled glass syringes. ISO Standard pre-filled glass syringes are supplied in multiple sizes. They fit with ISO Standard pre-filled glass syringes ranging from 0.5 mL to 5.0 mL of fill volume.

The guards are designed to meet the requirements specified in ISO 11040-4 Pre-filled syringes – Part 4 Glass barrels for injectables (March 1995).

Intended Use
The UltraSafe Passive™, X-Series, Needle Guard is intended for use as a safety mechanism designed to reduce the occurrence of accidental needlesticks to healthcare professionals during disposal of a used syringe and needle assembly. The UltraSafe Passive, X-Series, Needle Guard is snapped onto the barrel of an ISO Standard pre-filled glass syringe in a retracted position. Upon completion of the injection, the UltraSafe Passive, X-Series, Needle Guard passively activates and covers the exposed needle. When the Passive Needle Guard is activated, it aids in the prevention of accidental needlestick injury. The UltraSafe Passive™, X-Series, Needle Guard is intended for Intra-muscular (IM) or Subcutaneous (Sub-Q) injections. The healthcare professional then disposes the used syringe and needle assembly into a sharps container.

(Sub-Q) injections. The healthcare professional then disposes the used syringe and needle assembly into a sharps container.

The intended patient population is unrestricted and includes children and adults.

The intended environment of use is where healthcare professionals are required to administer medication, including vaccines, by means of a syringe.

Indications for Use

UltraSafe Passive™, X-Series, Needle Guards are single use devices that are indicated for use as an accessory with ISO Standard pre-filled glass syringes to aid healthcare professionals in the prevention of accidental needlesticks. The UltraSafe Passive™, X-Series, Needle Guard is intended for Intra-muscular (IM) or Subcutaneous (Sub-Q) injections.

This device is used on a wide range of patients, including children and adults.

Comparison of the UltraSafe® Injection System Needle Guard – B-Series to the UltraSafe Passive™, X-Series, Needle Guard

The UltraSafe Passive™, X-Series, Needle Guards are modifications of the previously cleared (K982878) UltraSafe Injection System Needle Guard, B-Series. The B-Series are manually activated needle guards. The X-Series are passively (automatically) activated needle guards.

The basic design, function, intended use, and indications for use of the B-Series and X-Series are similar.

Safety Syringes, Inc. conducted iterative user evaluations of the X-Series needle guard. A controlled simulated clinical use test was conducted with the UltraSafe Passive, X-Series, Needle Guard to validate the product in the hands of typical users. The UltraSafe Injection System Needle Guard, B-Series, was used as the control.

In the controlled simulated clinical use test, each of the specified acceptance criteria were either met or exceeded. The nurses involved in this study rated the X-Series to be equal to, or better than, the B-Series on all of the parameters related to safety, performance, and usability.

In addition to evaluating safety, performance, and usability parameters, there were questions of the study participants regarding the clarity and adequacy of the written and illustrated Directions for Use, and the participants' response to the need for in-service training. On each of the parameters, the X-Series rated as equal to, or better, than the B-Series.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2001

Mr. Thomas L. Hall
Director of Quality Assurance
Safety Syringes, Incorporated
1925 Palomar Oaks Way, #204
Carlsbad, California 92008

Re: K011369
Trade/Device Name: Ultrasafe Passive™ X-Series, Needle Guard Syringe, Piston (Accessory)
Regulation Number: 880.5860
Regulatory Class: II
Product Code: MEG
Dated: May 4, 2001
Received: May 4, 2001

Dear Mr. Hall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indications for Use Statement

510(k) Number: K011369

Device Name: UltraSafe Passive™
X-Series, Needle Guard
Syringe, Piston (Accessory)

Indications for Use:

UltraSafe Passive™, X-Series, Needle Guards are single use devices that are indicated for use as an accessory with ISO Standard pre-filled glass syringes to aid healthcare professionals in the prevention of accidental needlesticks. The UltraSafe Passive, X-Series, Needle Guard is intended for Intra-muscular (IM) or Subcutaneous (Sub-Q) Injections.

This device can be used on a wide range of patients, including children and adults.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Viola Hubbard for Pat Cucanta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011369

Prescription Use ✓ OR Over the Counter_____
(Per 21 CFR 801.109